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OPPOSED

**EDWIN BANKS' COMBINED REPLY IN SUPPORT OF MOTION FOR
SUMMARY JUDGMENT AND OPPOSITION TO
DEFENDANT'S CROSS-MOTION FOR SUMMARY JUDGMENT**

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Mr. Edwin Banks (“Mr. Banks”) files this combined reply on his own motion for summary judgment and opposition to the Defendant Alex Azar, in his official capacity as Secretary of Health and Human Services’ (the “Secretary”), cross-motion for summary judgment.¹ The Secretary’s opposition does not even address the elements of collateral estoppel until page 24 of a 30 page brief. In those six pages, the Secretary did not rebut Mr. Banks’ showing that the elements of collateral estoppel are met in this case. Further, the Secretary contends that, by moving for summary judgment based on collateral estoppel, Mr. Banks has “waived all other arguments” that go to the actual merits. (Def. Cross-Mot. Summ. J., Doc. 37 at 3, n. 2). There is simply no merit to that claim. Mr. Banks’ motion for summary judgment should be granted, the Secretary’s cross-motion denied, and this case remanded to the Secretary with instructions to provide coverage.

I. REPLY RE: NARRATIVE SUMMARY OF UNDISPUTED FACTS

Pursuant to this Court’s Order of April 28, 2020 (*See* Doc. 23), Mr. Banks’ motion for summary judgment set forth a separately numbered list of undisputed facts with an evidentiary citation for each one. (Pl. Mot. Summ. J., Doc. 31, pp. 3-5).

¹ Because the Secretary has cross-moved for summary judgment, Mr. Banks is abiding by this Court’s page limit requirements applicable to oppositions.

The Secretary did not dispute any of the facts set forth in his opposition or set forth any facts in support of the Secretary's own motion for summary judgment. Accordingly, pursuant to this Court's Order, the facts set forth in Mr. Banks' motion are deemed admitted and the Secretary has set forth no facts in support of his own cross-motion.

II. DISCUSSION

Nearly all of the Secretary's brief addresses issues other than the elements of collateral estoppel. Accordingly, in the interests of clarity, Mr. Banks will primarily address the elements of collateral estoppel before turning to the Secretary's other arguments.

A. The "Record"

The Secretary alludes to "evidence outside of the administrative record" and argues that such evidence should not be considered. (Def. Cross-Mot. Summ. J., Doc. 37, p. 10). Importantly, no such evidence is identified. To the extent the Secretary refers, *e.g.*, to the briefing below cited by Mr. Banks for the purposes of establishing that the Secretary had notice of proceedings before ALJ Gulin and that Mr. Banks was represented in those proceedings, those facts are deemed admitted because the Secretary did not comply with this Court's Order regarding disputing

facts. *See* Undisputed Fact Nos. 3-5 (“.. MAXIMUS was provided with notice of the hearing ...”) and No. 7 (“Mr. Banks was represented ...”).

In any event, regardless of the admission, the Court may properly consider these materials as set forth in Mr. Banks’ motion. *See* Pl. Mot. Summ. J., Doc. 31, pp. 17-18. The nature of collateral estoppel is that a final decision giving rise to collateral estoppel can occur *after* the non-final decision being estopped. Thus, at least partly because of the manner in which collateral estoppel may arise, judicial notice of other proceedings/decisions giving rise to collateral estoppel is common. Indeed, in similar circumstances, the Seventh Circuit took judicial notice of other proceedings to vacate an agency determination.

In *Opoka v. INS*, 94 F.3d 392 (7th Cir. 1996), the Seventh Circuit was “limited to reviewing the evidence that was before the BIA at the time it made its decision.” *Id.* at 394. However, after the BIA proceeding concluded, a relevant decision in another proceeding occurred. *Id.* (“After Mr. Opoka’s proceedings were concluded by the BIA, Mrs. Opoka was granted a suspension of deportation.”). Not only did the Seventh Circuit take judicial notice of these later proceedings to vacate and remand the BIA decision, the Seventh Circuit held that it would be “derelict” in its duty if it did not. *Id.* at 394-95.

Pursuant to 42 U.S.C. § 405(g), this Court may base its decision “upon the pleadings and transcript of the record.” Thus, this Court can properly consider the

materials cited by Mr. Banks as part of the “pleadings” in this case or simply as facts that have independent legal significance.

B. Collateral Estoppel May Be Based on a Later Issued Decision

As set forth in Mr. Banks' opening papers, where there is parallel/concurrent litigation, whichever case reaches finality first may have preclusive effect on the other (even first filed) litigation that is still ongoing. Pl. Mot. Summ. J., Doc. 31 at 7. *See also Adkins v. Nestle Purina Petcare Co.*, 779 F.3d 481, 484 (7th Cir. 2015) (“The first to reach final decision can affect the other ... through rules of claim and issue preclusion (res judicata and collateral estoppel)[.]”). Thus, the Secretary’s contention that collateral estoppel cannot apply because the final ALJ Gulin’ decision issued after the non-final ALJ Kelton’ decision is without basis.

C. The Standard of Review

The Secretary’s statements regarding the standard of review are incomplete. (Def. Cross-Mot. Summ. J., Doc. 37, p. 9). As set forth in 42 U.S.C. § 405(g), only the factual conclusions of the Secretary are subject to the “substantial evidence” standard. In all other respects, the Secretary’s decision is reviewed using any standard under the Administrative Procedure Act/federal law. *See, e.g., Friedman v. Sebelius*, 686 F.3d 813, 826-27 (D.C. Cir. 2012) (applying arbitrary and capricious standard). Likewise, as detailed above, and in Mr. Banks’ motion (Pl. Mot. Summ.

J., Doc. 31, pp. 17-18), this Court may take judicial notice of matters related to collateral estoppel.

On pages 11-12 of the Secretary's Cross-Motion, he alleges: "The court's review is limited to the record that was before ALJ Kelton." (Def. Cross-Mot. Summ. J., Doc. 37, p. 11). No basis for such claim exists. Under 42 U.S.C. § 405(g), the Court's review may be based on the pleadings and "the transcript of the record." The "transcript of the record" includes all the proceedings before the Department, including those before the Departmental Appeals Board ("DAB"). As the Secretary admits, ALJ Gulin's decision is part of the record in this case. *See* Def. Cross-Mot. Summ. J., Doc. 37, at 12; CAR1267-79. Thus, the Court may properly consider ALJ Gulin's decision as part of the "record", in addition to the Court's power to take judicial notice of the decision.

Citing *Cross Terrace Rehab., Inc., LLC v. Secretary of H.H.S.*, 797 Fed.Appx. 503, 507 (11th Cir. 2020), the Secretary further alleges that the Court should only consider "the facts known to the agency at the time the decision was made." Def. Cross-Mot. Summ. J., Doc. 37, at 11. Clearly, that is a contention without basis. First, of course, at the time the Council made the decision to let ALJ Kelton's decision stand (by failing/refusing to issue its own decision), the Council knew of the fact of ALJ Gulin's decision. *See* CAR1267-79. Second, as advanced by the Secretary, a final decision in one case could not have preclusive effect on the non-

decision in another case. That is contrary to, *e.g.*, the Supreme Court’s decisions in *Kline* and *Elder* holding that where parallel/concurrent litigation is present, whichever case reaches finality first may have preclusive effect on the other. Mot. at 7. Because of this standard, it is evident that cases will arise where after a non-final decision is made, a final decision arises that may be controlling. Thus, the Court’s review is not limited to the facts known to either ALJ Kelton or the Council.

D. Collateral Estoppel Applies

As set forth by the Supreme Court in *Astoria*, there is a presumption that collateral estoppel applies when an agency is acting in a “judicial capacity” and all the other elements of collateral estoppel are present. *See Astoria Federal Savings and Loan Assoc. v. Solimino*, 501 U.S. 104, 108 (1991) (“[W]here a common-law principle is well established, as are the rules of preclusion, the court may take it as a given that Congress has legislated with an expectation that the principle will apply except when a statutory purpose to the contrary is evident.”) (internal citations and quotations omitted).

With regard to the elements of collateral estoppel, the Secretary did not rebut Mr. Bank’s showing that each of them is present.

1. The Issue at Stake is Identical to the One Involved in the Prior Proceeding

As discussed above, in Mr. Banks’ moving papers, Mr. Banks set forth a series of undisputed facts in compliance with this Court’s Order. Several of those facts

relate to what issues were the subject of both ALJ Gulin and ALJ Kelton's decisions. *See* Pl. Mot. Summ J., Doc. 31, Undisputed Fact Nos. 10 ("At issue ..."), 12, 18, and 20. As set forth, those facts state identical issues in ALJ Gulin and ALJ Kelton's decisions. However, the Secretary's opposition did not comply with the Court's Order to dispute any of those facts. Thus, as a matter of procedure, those facts may be deemed admitted. Because the admitted facts are identical as between ALJ Gulin's and ALJ Kelton's decisions, the element is proven.

Putting aside the procedural admission, the Secretary has not shown that the issues at stake were not identical. It is well settled that the test for determining whether facts/issues are the same between two decisions for collateral estoppel purposes is "materiality." That is, facts/issues are the same unless they are materially different with respect to the conclusions reached (*i.e.*, "changed circumstances"). *See, e.g., Montana v. U.S.*, 440 U.S. 147, 159 (1979) ("changes in facts essential to a judgment will render collateral estoppel inapplicable"); *Bernstein v. Bankert*, 733 F.3d 190, 226 (7th Cir. 2013) ("identical in all material aspects"); *Scooper Dooper, Inc., v. Kraftco Corp.*, 494 F.2d 840, 846 (3rd Cir. 1974).

In the present case, the Secretary has not shown that there is a material difference between TTFT coverage for Mr. Banks between, *e.g.*, February 2018 (when ALJ Gulin found it was covered) and March 2018 (when ALJ Kelton found it was not covered). There is no evidence that TTFT got any less safe and effective,

less life-extending, less “medically reasonable and necessary” for Mr. Banks, or less of a Medicare covered benefit in the passage of one month.

Of course, both ALJ Gulin and ALJ Kelton could only decide the claims for coverage before them. Thus, the fact that each decision describes the months that it relates to says nothing about whether the same issues were at stake. As shown, they were.

The Secretary’s reliance on *Applied Medical Resources Corp. v. United States Surgical Corp.*, 435 F.3d 1356, 1361-62 (Fed. Cir. 2006) is particularly off-base. *Applied* is a patent case discussing reasonable royalties. Under Federal Circuit precedent (absent an established royalty), a reasonable royalty is based on the rate the parties would have accepted in a hypothetical negotiation taking place just before the infringement began. *Id.* at 1361 (“must relate to the time the infringement occurred”). Thus, the reasonable royalty determined in one case for infringement beginning on one date cannot collaterally estop either party from arguing for a different reasonable royalty for separate acts of infringement beginning on a different date at issue in a later case.

The identical issues of whether TTFT was medically reasonable and necessary and a Medicare covered benefit for Mr. Banks was at stake in both cases.

2. The Issue Was Actually Litigated in the Prior Proceeding

The Secretary asserts that the same issue was not actually litigated in the prior proceeding for the same reason the Secretary asserts identical issues were not at stake. – i.e., each decision concerns different months of coverage. Def. Cross-Mot. Summ J., Doc. 37. at 25-26.

That claim is addressed above and Mr. Banks’ showing that the issues of “medically reasonable and necessary” and “Medicare covered benefit” were actually litigated before ALJ Gulin has not been rebutted.

3. The Determination in the Prior Litigation Was a Critical and Necessary Part of the Judgment

The Secretary’s opposition does not address this element of collateral estoppel and Mr. Banks’ showing is unrebutted.

4. The Secretary Had a Full and Fair Opportunity to Litigate

As shown in Mr. Banks’ opening papers, where the beneficiary is represented (as Mr. Banks was), the Secretary has the full panoply of rights of a litigant. Pl. Mot. Summ. J., Doc. 31, at 23-24. Further, “notice and opportunity” is the foundation of the “full and fair opportunity to litigate” element. *Id.* (citing *Mullane v. Cant. Hanover Bank & Tr. Co.*, 339 U.S. 306, 314 (1950)). Here, again, because the Secretary did not contest Mr. Banks’ facts, it admitted both that Mr. Banks was represented and that the Secretary had notice of the proceedings before ALJ Gulin.

See Pl. Mot. Summ. J., Doc. 31, Undisputed Fact Nos. 1-7. Accordingly, the Secretary had a full and fair opportunity to litigate.

The Secretary's comments with regard to this issue are a series of strawmen. Def. Cross-Mot. Summ. J., Doc. 37, at 26-27. First, the Secretary contends that he has had no opportunity to participate in levels below the ALJ. Pursuant to *Astoria and Utah Construction Co.*, 384 U.S. 394, 422 (1966), collateral estoppel only applies when a department/agency is acting in a "judicial capacity." In proceedings below the ALJ level (*i.e.*, initial denial, redetermination, and reconsideration), the Secretary is not acting in a "judicial capacity", so whether the Secretary has a role there or not is irrelevant. By contrast, clearly, both the ALJs and the Council are the Secretary acting in a "judicial capacity" and may form the basis for collateral estoppel.

Second, the Secretary's comments regarding unrepresented parties are irrelevant. As noted and admitted, Mr. Banks was represented and the Secretary had the full panoply of rights of any litigant. Pl. Mot. Summ. J., Doc. 31, at 23-24. Thus, the Secretary had all the rights of any litigant, including appeal. *See* 42 C.F.R. §§ 405.1100-1140. Indeed, regardless of what the Secretary chose to do before the ALJ, the Secretary could have appealed on so-called "own motion review." *See* 42 C.F.R. § 405.1110. It is simply untrue to say that the Secretary had an "extremely limited" opportunity to appeal. Def. Cross-Mot. Summ. J., Doc. 37, at 27.

That the Secretary choose not to take advantage of any of these rights does not preclude the application of collateral estoppel. Indeed, it simply means that before ALJ Gulin, Mr. Banks was put to his burden of proof, met that burden, the Secretary did not appeal, and the decision has now become final. Now, the Secretary seeks to force Mr. Banks to repeat that exercise on the identical issues. That is precisely the instance in which collateral estoppel applies.

Mr. Banks' showing that all the elements of collateral estoppel are present was not rebutted.

E. The Secretary's Other Comments

As noted above, there is a presumption that collateral estoppel applies when an agency is acting in a "judicial capacity" and all the other elements of collateral estoppel are present. *Astoria*, 501 U.S. at 108. The Secretary did not rebut that presumption.

1. The Secretary's Comments Regarding LCDs

On pages 3-8 of the Secretary's Response/Cross-Motion for Summary Judgment, the Secretary sets forth various background information. A response to

most of it is unnecessary and the entire section seems irrelevant to the issue of collateral estoppel. That said, a few comments are either erroneous or incomplete.²

It is true that local coverage determinations (LCDs) are supposed to be developed by considering medical literature, etc. and be reviewed to ensure that they do not become outdated. Def. Cross-Mot. Summ. J., Doc. 37, at 5-6. However, unmentioned in the Secretary's paper is that did not happen in the case of TTFT. That is, the LCD that became effective on October 1, 2015 did not consider the suspension of the clinical trial in 2014 on the grounds that withholding TTFT from the control group would have been unethical. Likewise, the LCD was not reviewed after its issuance and did not consider the large number of scientific studies showing the effectiveness of TTFT, additional FDA approval in October 2015, the fact that TTFT had become the standard of care for GBM no later than 2018, as well as clinical trials and seminal papers concerning the same.

Because of this complete failure of process, in May 2019, ALJ Scott Anderson determined that the 2015 LCD concerning TTFT was not supported by substantial evidence. *See* Pl. Mot. Summ. J., Doc. 31, at 16. The Secretary's claim that this decision was a result of a "request" from Novocure (Def. Cross-Mot. Summ. J., Doc.

² The Secretary's citation to various sections of the Medicare Program Integrity Manual (MPIM) is also in error. The sections cited by the Secretary were adopted in 2019 while the LCD relevant to the present claims was adopted in 2015.

37, at 6) to approve payment for newly diagnosed GBM is false. Instead, ALJ Anderson's decision was the result of an LCD challenge by a Medicare beneficiary (*i.e.*, the "Aggrieved Party") contending that the LCD was not supported by substantial evidence. Thereafter, the Contractor submitted a revised LCD (that is also being challenged) that only applies to dates of service after September 1, 2019.

2. There is No Statutory Purpose to the Contrary

The Secretary asserts that collateral estoppel cannot apply when there is a statutory purpose to the contrary. Def. Cross-Mot. Summ. J, Doc. 37, at 13. The only statute discussed by the Secretary in this regard refers to Council consideration of ALJ appeals "*de novo*." *Id.* at 17 (*citing* 42 U.S.C. § 1395ff(d)(2)(B)). Other than the *de novo* review provision, the Secretary merely cites to his own regulations as demonstrating an alleged contrary purpose. *Id.* at 13-17. Of course, regulations are not statutes - so they have no relevance in this regard.

With respect to *de novo* review by the Council, that does not indicate a purpose contrary to collateral estoppel. "*De novo*" review merely means that the reviewing court conducts its review "independent, with no deference given to the trial court's conclusion." *See, e.g., In re: Deitz*, 760 F.3d 1028, 1043 (9th Cir. 2014). Thus, the reviewing court decides matters in the same stead as the court/tribunal appealed from without any deference to the conclusions reached by the court/tribunal being reviewed.

Of course, such *de novo* review does not mean the reviewing court can proceed without regard to any legal principles/doctrines. Courts routinely apply collateral estoppel in matters subject to *de novo* consideration/review. Indeed, orders granting summary judgment based on collateral estoppel are subject to *de novo* appellate review, as is the application of collateral estoppel itself. *See, e.g., Miccosukee Tribe of Indians v. U.S. Army Corps of Engineers*, 619 F.3d 1289, 1296 (11th Cir. 2010) (“We review the district court’s invocation of collateral estoppel *de novo*.”); *Mike Smith Pontiac, GMC, Inc., v. Mercedes-Benz of North America, Inc.*, 32 F.3d 528, 522 (11th Cir. 1994) (“We review *de novo* a grant of summary judgment on grounds of collateral estoppel”). The Secretary’s position that collateral estoppel can never apply wherever there is *de novo* review is obviously incorrect.

The Secretary’s citation to *Almy v. Sebelius*, 679 F.3d 297 (4th Cir. 2012) is inapposite that case involved only an “arbitrary and capricious” review across multiple cases (and apparently different plaintiffs) and not collateral estoppel.

3. The Secretary’s Comments on “Precedential” Decisions and Collateral Estoppel Are Misguided

Respectfully, it is difficult to follow the Secretary’s comments regarding “precedential” decisions and collateral estoppel. Def. Cross-Mot. Summ. J., Doc. 37, at 15-16. Apparently, in the Secretary’s view, decisions that are “precedential”

and those giving rise to “collateral estoppel” are synonymous. This reflects a fundamental misunderstanding of the distinct legal concepts at issue.

A “precedential” decision is binding on all lower courts/decision makers, regardless of the parties before the lower court/decision maker. *See, e.g., Alleghany General Hospital v. National Labor Relations Board*, 608 F.2d 965, 969-70 (3rd Cir. 1979). By contrast, “collateral estoppel” focuses on the issues and parties to an earlier litigation and binds those parties in a subsequent litigation of the same issues regardless of the level of review, if any.

Recognizing the difference between a decision having “precedential effect” and a decision giving rise to collateral estoppel, prior to the adoption of FED.R.APP.P. 32.1(a) in 2006, numerous federal appellate courts enacted local rules that precluded citation to non-precedential decisions except when cited, *inter alia*, for purposes of collateral estoppel. *See, e.g.,* 7th Cir. Rule 32.1(b)/(d) (“Every order bears the legend: ‘Nonprecedential disposition.’”); (“No order of this court issued before January 1, 2007, may be cited except to support a claim of preclusion (res judicata or collateral estoppel) or to establish the law of the case from an earlier appeal in the same proceeding.”).

Simply put, “precedence” and “collateral estoppel” are distinct legal concepts and “precedence” has no bearing on this case.

4. Collateral Estoppel Would Not Interfere With Discretion

On pages 18-22, the Secretary presents a broad argument that his actions are immune from the opinions of the Supreme Court (*Astoria* and *Utah Construction*) or any legal principles because that would interfere with the Secretary's "discretion" to implement the Medicare Act. Indeed, the Secretary offers that he has discretion to "not be bound by ALJ rulings." Def. Cross-Mot. Summ. J., Doc. 37, at 18. In support of this position, the Secretary cites a mishmash of cases, involving disparate facts and irrelevant issues, and quotes various passages from such cases out of context.

Pursuant to *Astoria* and *Utah Construction*, collateral estoppel only applies when a department/agency is acting in a "judicial capacity." Thus, the Secretary's citations to, and quotes from, *Devon Energy Corp. v. Kempthorne*, 551 F.3d 1030 (D.C. Cir. 2008) and *Comcast Corp. v. F.C.C.*, 526 F.3d 763 (D.C. Cir. 2008), are not relevant because they involve only non-judicial proceedings/statements by agencies. See *Devon*, 551 F.2d at 1040 (Royalty Policy Board statements); *Comcast*, 526 F.2d at 769 (FCC Media Bureau waivers).

Along these same lines, the Secretary cites and quotes from multiple cases concerning the Provider Reimbursement Review Board (PRRB).³ The PRRB is not

³ *Community Care Foundation v. Thompson*, 318 F.3d 219, 227 (D.C. Cir. 2003); *Homan & Crimen, Inc. v. Harris*, 626 F.2d 1201, 1205 (5th Cir. 1980) (non-final decision of PRRB, "a five-member panel of experts"); *Abraham Lincoln Memorial Hospital v. Sebelius*, 698 F.3d 536, 556 (7th Cir. 2012).

composed of ALJs. Instead, the PRRB is a five-member panel of “persons knowledgeable in the field of healthcare reimbursement” (42 C.F.R. § 405.1817) charged with reviewing accounting decisions of contractors regarding reimbursements to providers. In the words of the Seventh Circuit, the PRRB is comprised of “minions” within the Department. *Homemakers North Shore, Inc. v. Bowen*, 832 F.2d 408, 413 (7th Cir. 1987). Thus, again, the PRRB is not an instance of the Department acting in a “judicial capacity” and these cases are irrelevant.

As to the Secretary’s allegation that applying collateral estoppel would interfere with his discretion to decide matters by promulgating rules or by individual adjudication (Def. Cross-Mot. Summ. J., Doc. 37, at p. 18), there is nothing to that. Where the Secretary has elected to proceed by individual adjudication, applying collateral estoppel would not interfere with that choice. Instead, it would only mean that collateral estoppel may, or may not, apply as to that particular plaintiff in that individual adjudication.

For example, the next time that Mr. Banks submits a claim for coverage of his TTFT device, that matter will be individually adjudicated. Based on his earlier favorable decisions, Mr. Banks will assert that (absent changed circumstances) the Secretary is collaterally estopped from denying that TTFT is a covered Medicare benefit for him/is “medically reasonable and necessary.” Indeed, absent changed circumstances, that will be the case in all future claims by Mr. Banks.

The Secretary's citation to *Int'l Rehab Sci. Inc. v. Sebelius*, 688 F.3d 994, 1001 (9th Cir. 2012) (Def. Cross-Mot. Summ. J., Doc. 37, at p. 21) is inapposite because that case involved only an "arbitrary and capricious" review across multiple cases and not collateral estoppel. Likewise, inapposite is the Secretary's out of context citation to, and quotation from, *Freeman v. U.S. Dep't of Interior*, 37 F.Supp.3d 313, 344-45 (D.D.C. 2014). *Id.* The court' comments that the Secretary references from that decision were in the context of a plaintiff that argued that prior ALJ decisions to which it was not a party "bound" the Department in a non-mutual, collateral estoppel sense. Citing *Mendoza*, the court there properly rejected that assertion. *Freeman*, F. Supp. 3d. at 346 ("Under these circumstances, the general rule amply applies and no non-mutual preclusive effect is warranted for the ALJ rulings in *Aloisi* and *Story*."). As already shown, such reasoning is inapplicable where mutuality exists.

The Secretary's discussion of *Almy* is likewise inapposite. Def. Cross-Mot. Summ. J., Doc. 37, at p. 20. As indicated, *Almy* concerned only an "arbitrary and capricious" review across multiple cases (and apparently different plaintiffs) by a plaintiff seeking coverage for "future claims." Thus, the comments there were in the context of those issues and not collateral estoppel.

Collateral estoppel does not interfere with the Secretary's discretion to implement the Medicare Act by individual adjudication.

5. The Secretary’s “Future Claims,” Presentment,” and “Channeling” Comments Misapprehend this Case

The Secretary offers a number of comments regarding “future claims” by Mr. Banks as well as the requirement to present claim to the Secretary and to channel them through the claims process. Def. Cross-Mot. Summ. J., Doc. 37, at 22-24. These comments misapprehend the entire basis of this case and the relief sought.

As set forth in the Complaint, Mr. Banks seeks only relief for the denied claims that are at issue in this case and no prospective relief of any kind is sought. That is, Mr. Banks seeks only a determination regarding the claim that is the subject of ALJ Kelton’s decision and seeks no relief with respect to any “future claims” Mr. Banks may have. Whether collateral estoppel will apply to any future claims by Mr. Banks will depend on the facts and circumstances at the time those claims are made. Accordingly, the Secretary’s comments in this regard are simply irrelevant.

Likewise irrelevant are the Secretary’s comments regarding *Porzecanski, v. Azar*, 943 F.3d 472 (D.C. Cir. 2019) (Def. Cross-Mot. Summ. J., Doc. 37, at p. 22). In *Porzecanski*, the plaintiff sought an injunction mandating coverage of any “future claims” the plaintiff might submit. *Id.* at 475 (“prospective equitable relief”). By contrast, Mr. Banks seeks only retrospective relief.⁴

⁴ As set forth in the Complaint, a case like this technically seeks “injunctive relief” not “damages” (*i.e.*, an injunction requiring the Secretary to provide coverage for the claims at issue). *See Bowen v. Massachusetts*, 487 U.S. 879, 893-901 (1988).

Further, the Secretary's reading of the *Porzecanski* case is erroneous. Opp. at 22-24. In *Porzecanski*, the plaintiff both appealed the denial of a Medicare claim and sought declaratory and injunctive relief regarding any "future claims" he might submit. While reversing the denial of coverage for the claim at issue, the district court concluded that it could not issue declaratory and injunctive relief as to possible "future claims." Only the denial of declaratory and injunctive relief as to "future claims" was the subject of appeal and the district court's decision as to the claim actually denied was not at issue. *See Porzecanski*, 943 F.3d at 477-78.

With that background, the Secretary's contention that *Porzecanski* said anything about preclusion with regard to the "claims on appeal" (Def. Cross-Mot. Summ. J., Doc. 37, at 23) is simply false. *Porzecanski* said nothing about collateral estoppel or preclusion with respect to the claim actually appealed to (and reversed by) the district court and only concerned the request for prospective relief.

Along these same lines, the Secretary offers comments regarding the possible impact on future claims of a revised LCD that applies to services provided after September 1, 2019. Def. Cross-Mot. Summ. J., Doc. 37, at pp. 28-30. These comments are irrelevant. Whether the revised LCD may impact potential "future claims" by Mr. Banks is not a matter before this Court. Instead, Mr. Banks only seeks relief with respect to ALJ Kelton's decision covering dates of service in January, March, and April 2018.

6. The Secretary's Comments Regarding Appeal Volumes

In various places, the Secretary asserts that it is “impractical”/“inefficient” for the Secretary to participate in ALJ appeals and that, therefore, it would be unfair to apply collateral estoppel to the Secretary. Def. Cross-Mot. Summ. J., Doc. 37, at 27. In support of that claim, the Secretary asserts “it is impractical for the Secretary to litigate hundreds of thousands of appeals annually” (citing a January 17, 2017 Federal Register publication). The Secretary’s factual claims are erroneous and his argument is unavailing.

This is not the only litigation Secretary is involved in. One of the other cases is *American Hospital Assoc. v. Sebelius*, Case No. 14-cv-851-JEB, (D.D.C.). There, the Court issued a *writ of mandamus* ordering the Secretary to reduce the backlog of cases pending before ALJs according to a schedule and to provide status reports of the Secretary’s progress to the Court. On March 25, 2020, the Secretary filed his latest status report in the D.C. case, attached hereto as Exhibit A.

As shown in the status report, in FY2019, 43,887 appeals were filed at the ALJ level. *See* Exhibit A.⁵ In Plaintiffs’ view, even ~44,000 appeals substantially

⁵ As shown in Exhibit A, the number of appeals filed at the ALJ level has fallen dramatically, every year for the last five years. In 2013 and 2014, the Secretary conducted very aggressive audits of hospital charges for in-patient care and retroactively denied hundreds of thousands of claims, which were appealed (referred to in the materials as “RAC” appeals). This spike appears to be the reason that the Secretary choose to offer data from a period 5-6 years ago rather than data that is readily available to the Secretary showing appeals filed through the end of March 2020.

overstates the relevant figure because it includes appeals of all kinds, the vast majority of which are hospital/provider appeals.

This is a “beneficiary appeal”, *i.e.*, an appeal by Mr. Banks as opposed to an appeal by a hospital/provider that is likely have much more substantial resources than Mr. Banks and for whom delay is less of a burden. The Secretary has published data for FY2019 indicating that 5,148 beneficiary appeals were filed at the ALJ level.⁶ Indeed, even that figure is overstated because it includes appeals in Social Security cases.

Even a figure limited to Medicare beneficiary appeals would likely overstate the true number. Though the Secretary has published no data, it is believed that the vast majority of Medicare beneficiary appeals are by unrepresented beneficiaries (*i.e.*, with no lawyer present).⁷ In such appeals, the Secretary may not participate as a party. Thus, as detailed above, it is simply incorrect to say that the Secretary litigates or would have to litigate “hundreds of thousands of appeals annually” under any standard.

Even assuming that every one of the ~5,000 beneficiary appeals was by a represented party, that would not demonstrate that the application of collateral

⁶ <https://www.hhs.gov/about/agencies/omha/about/current-workload/beneficiary-appeals-data/index.html> (visited April 24, 2020).

⁷ Whether collateral estoppel can or should apply in those cases is a matter for another day.

estoppel was unfair. Where the beneficiaries have retained counsel to litigate their claims, not applying collateral estoppel would be unfair and would merely result in all the evils collateral estoppel exists to avoid (expense and burden on the courts and parties, inconsistent results).

To the extent that the Secretary alleges that it would be inefficient for the Secretary to litigate these cases, there is no support for that claim. Indeed, not applying collateral estoppel would be inefficient. For example, here, Mr. Banks retained counsel and fully litigated the issue of TTFT coverage. Thereafter, an ALJ held a hearing and issued a written decision on the matter. If collateral estoppel is applied, that should largely be the end of the matter going forward (*i.e.*, as long as there are not changed circumstances). By contrast, the Secretary proposes an indefinite investment of resources (by both Mr. Banks and the Secretary himself through the ALJ) to litigate the identical issues. Avoiding that is the very purpose of collateral estoppel.

7. The Secretary's Lack of Incentive Argument

The Secretary nearly closes his discussion of collateral estoppel attempting to invoke the “lack of incentive to litigate” exception to collateral estoppel. Def. Cross-Mot. Summ. J., Doc. 37, at pp. 27-28. As explained by the Supreme Court in *B & B Hardware, Inc. v. Hargis Indust., Inc.*, 575 U.S. 138 (2015), collateral estoppel may be “inapt if the amount in controversy in the first action was so small in relation to

the amount in controversy in the second that preclusion would be plainly unfair.” *Id.* at 159. Likewise, in *Parklane*, the Supreme Court indicated that if the amount in the first action is so small, a party may have little incentive to litigate “particularly if future suits are not foreseeable.” *Parklane*, 439 U.S. at 330.

While discussing the exception, the Secretary never makes any effort to demonstrate how it applies here. First, there is no material disparity between the amounts at stake in both the decision forming the basis for collateral estoppel and the decision being appealed. Indeed, the stakes are identical in that all of the decisions concern particular months of coverage. Thus, the Secretary had the same incentive to litigate before ALJ Gulin as he did before ALJ Kelton. Second, given that the TTFT device is rented on a monthly basis and that claims will be submitted as long as Mr. Banks is alive, clearly, future claims/suits were foreseeable.

To the extent that the Secretary’s point is that he just did not care about the earlier case because he did not consider it significant, that demonstrates that the application of collateral estoppel is fair. Because they concern identical issues, each claim by Mr. Banks is just as important as the others. If the Secretary did not care about the earlier case, then there is no reason not to apply collateral estoppel to the present case because the Secretary still does not care.

The Secretary had every incentive to litigate and the application of collateral estoppel would not be unfair. Mr. Bank’s motion should be granted.

F. The Secretary's Cross-Motion Should Be Denied

Respectfully, it is unclear what “cross-motion” the Secretary alleges. To the extent that the “cross-motion” is simply a request that Mr. Banks’ motion should be denied, that is without basis as detailed above.

To the extent that the “cross-motion” is a motion for summary judgment of every other issue in this case (on the alleged grounds of waiver), there is no merit to that proposition and it should be denied. Moreover, respectfully, that reflects a serious misunderstanding of the procedural posture of this case.

As detailed in the Complaint, Mr. Banks has a number of causes of action alleging that the Secretary’s denial of his claim fails to comply with the law under various sections of the APA. Simply as an example, Mr. Banks alleges that the decision should be reversed because it is “arbitrary and capricious.” In support of those causes of action, Mr. Banks asserts that the Secretary is collaterally estopped from denying coverage. However, should the Court decide against Mr. Banks on this ground, it would merely mean that the Secretary was not estopped. Mr. Banks’ causes of action would remain to be resolved with each side bearing its burdens of proof.

Both parties have merely moved for summary judgment as to whether collateral estoppel applies without addressing the substantive merits of the underlying claims. In Mr. Banks’ case, the very purpose of asserting collateral

estoppel is so that he does not have to bear the burden of relitigating the issues, avoiding waste of judicial resources, and avoiding inconsistent results. If Mr. Banks' motion for summary judgment is denied, the merits of the underlying claim will remain to be addressed.

III. CONCLUSION

The triple purposes of collateral estoppel would be served by its application in this case. First, Mr. Banks has already been the subject of multiple ALJ decisions and has had to bear the costs, delays, and uncertainties of that repeated litigation. Second, if collateral estoppel is not applied, Mr. Banks alone could be the source of as many as four (4) cases on this Court's docket each year.⁸ Third, the application of collateral estoppel would prevent inconsistent results, as demonstrated in this case (*e.g.*, February 2018 is covered, March and April 2018 are not covered, May 2018-Janaury 2019 is covered).

For the reasons set forth above, Mr. Banks' motion should be granted. The Court should hold that the Secretary is collaterally estopped from denying that TTFT is medically reasonable and necessary and a Medicare covered benefit for Mr. Banks, reverse the decision of ALJ Kelton, and remand this case with instruction to

⁸ Because claims for coverage are typically submitted every three months.

order coverage of the claims at issue. The Secretary's cross-motion should be denied.

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CERTIFICATE OF SERVICE

I hereby certify that on June 25, 2020 I filed the foregoing with the Clerk of Court via the CM/ECF electronic filing system which will send electronic notice of the foregoing pleading to all counsel of record.

/s/ Robert R. Baugh
OF COUNSEL